Medicare Learning Network
MLN Matters®
CMS
Information for Medicare Fee-For-Service Health Care Professionals

News Flash – Medicare Fee-For-Service (FFS), and its business associates, will implement the ASC X12, version 5010, and NCPDP, version D.0, standards as of January 1, 2012. To facilitate the implementation, Medicare has designated calendar year 2011 as the official 5010/D.0 transition year. As such Medicare Administrative Contractors (MACs) will be testing with their trading partners throughout calendar year 2011. Medicare encourages its providers, vendors, clearinghouses and billing services to schedule testing with their local MAC as soon as possible. Medicare also encourages you to stay current on 5010/D.0 news and helpful tools by visiting http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/index.html on its website. Test early, Test often!

MLN Matters® Number: MM7249
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Related CR Transmittal #: R2113CP
Implementation Date: January 12, 2011

Payment for 510k Post-Approval Extension Studies Using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

Note: This article was updated on September 4, 2012, to reflect current Web addresses. All other content remains the same.

Provider Types Affected

This article is for physicians, hospitals, or other providers who submit claims to Medicare Carriers, Fiscal Intermediaries (FIs), or Medicare Administrative Contractors (A/B MACs) for providing Carotid Artery Stenting (CAS) procedures, in post approval extension studies, using 510k-cleared embolic protection devices.

What You Need to Know

CR 7249, from which this article is taken, announces that, effective October 22, 2010, the Centers for Medicare & Medicaid Services (CMS) has determined that all 510k post-approval extension studies must be reviewed by the Food and Drug Administration (FDA) via its Pre-Investigational Device Exemption (IDE) process.

It specifically discusses the coverage of proximal embolic protection devices (EPDs) used in carotid artery stenting (CAS) procedures performed in FDA-approved 510K post-approval extension studies, announcing that these patients (similar to patients covered in traditional post-approval extension studies) are eligible for coverage under the current coverage policy.

In order to receive Medicare coverage for patients participating in these 510k post-approval extension studies, you will need to follow the same billing processes as explained in the Medicare Claims Processing Manual, Chapter 32 (Billing Requirements for Special Services), Section 160.2.1 (CAS for Post-Approval Studies), except that you should report 510k-cleared devices with a pre-IDE number beginning with an "I", instead of an IDE number beginning with a "P" (post-market approval). You can find this manual section at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf on the CMS Website.

You should make sure that your billing staffs are aware of these coverage changes.

Background

In 2004, CMS gave Medicare contractors instructions on processing claims for CAS procedures performed in FDA-approved post-approval studies. (Please refer to MLN Matters® article MM3489, released on October 15, 2004, entitled Percutaneous Transluminal Angioplasty (PTA), which you can find at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3489.pdf on the CMS Website).

As these post-approval studies began to end, CMS received requests to extend coverage for them. On May 12, 2006, CMS released Change Request (CR) 5088 which updated the Claims Processing Manual and explained that patients participating in post-approval extension studies are also included in the covered population of patients participating in FDA-approved post-approval studies. CR 5088 also provided claims processing instructions specific to post approval extension studies. (Please refer to MLN Matters® article MM5088 entitled Payment for Carotid Artery Stenting (CAS) Post Approval Extension Studies, which you can find at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5088.pdf on the CMS Website and to the Medicare National Coverage Determinations (NCD) Manual, Chapter 1 (Coverage Determinations), Section 20.7 (Percutaneous Transluminal Angioplasty (PTA)), which is available at http://www.cms.gov/Regulations-and-

Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf on the CMS Website.

Coverage of Proximal Embolic Protection Devices (EPDs) in Carotid Artery Stenting (CAS) Procedures

Recently, the FDA issued 510k approvals for proximal EPDs used in CAS procedures. However, while the NCD requires use of an EPD, the 510k process (unlike traditional FDA marketing approval requirements) does not involve a post-approval study requirement; and CMS received requests to include, under the current coverage policy, patients participating in studies that followed FDA 510k approval of these devices.

In response, effective October 22, 2010. CMS determined that patients in these studies (similar to patients covered in traditional post-approval extension studies as discussed above) are eligible for coverage under the current coverage policy referenced in Section 20.7 in the NCD Manual referenced above.

Moreover, while the FDA does not require devices approved through the 510k process to undergo further study following clearance (as such, these studies are neither required by, nor subject to, FDA approval), CMS has determined that the FDA must review all 510k post-approval extension studies through its pre-IDE process. As a result of this process, each study is assigned, and identified by, a single, 6-digit number preceded by the letter 'I' (i.e., I123456). (For example, the FREEDOM study, examining the 510k-cleared Gore Flow Reversal System, was assigned I090962, and must be identified as such on all claims.)

Notification Process

Following this review process, the FDA will issue CMS an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. CMS, upon receipt of this letter and review of the 510k post-approval extension study protocol, will issue a letter to the study sponsor indicating that Medicare will cover the study under review.

Billing

Your carrier, FI, or A/B MAC will follow the same procedures for processing post-approval study devices that are currently in place for Category B IDEs. In order to receive Medicare coverage for patients participating in 510k post-approval extension studies, you will need to submit both the FDA acknowledgement letter and the CMS letter providing coverage for the extension study to your contractor, and any other materials they might require for FDA-approved post-approval studies or post-approval extension studies. Further, you should follow the process (as established in CR 3489) for informing them of the patients' participation in the

studies, utilizing the most current and appropriate codes when submitting your claims. This process is as follows:

1. For billing carriers, you should:

- Place the IDE number (that begins with an "I") in either item 23 of the CMS-1500 paper claim format or in the 2300 IDE Number Ref Segment, data element REF02 (REF01=LX) of the 837p claim format;
- Use the Q0 modifier, instead of QA;
- Use the most current ICD-9-CM procedure codes;
- Use the most current ICD-9-CM diagnostic codes.

2. For billing FIs, you should:

- Use the most current ICD-9-CM procedure codes;
- Place no more than one IDE number (that begins with an "I") in form locator 43 of the CMS-1450 paper form or in 2300 IDE Number Ref Segment, data element REF02 (REF01=LX) of the 837i;
- Use revenue code 0624 for post-approval study devices in form locator 42 of the CMS-1450 paper claim form or 2400 Institutional Service Line SV201 Segment, data element 234 of the 837i;
- Use the most current ICD-9-CM diagnostic codes.

You should also be aware that your contractor is not required to mass-adjust claims for dates of service between the October 22, 2010, effective date and this CR's implementation date, but they may adjust claims that you bring to their attention.

Additional Information

You can find more information about payment for 510k Post-Approval Extension Studies using 510k-cleared EPDs during CAS procedures by going to CR 7249, located at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2113CP.pdf on the CMS Website.

You will find the updated Medicare Claims Processing Manual, Chapter 32 (Billing Requirements for Special Services), Section160.4 (510k Post-Approval Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures) as an attachment to that CR.

If you have 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.