MLN Matters®
Information for Medicare Fee-for-Service Health Care Professionals

News Flash - News Flash - The fifth annual national administration of the Medicare Contractor Provider Satisfaction Survey (MCPSS) is now underway. If you received a letter indicating that you were randomly selected to participate in the 2010 MCPSS, CMS urges you to take a few minutes to go online and complete this important survey via a secure Internet website. Responding online is a convenient, easy, and quick way to provide CMS with your feedback on the performance of the FFS contractor that processes and pays your Medicare claims. Survey questionnaires can also be submitted by mail, secure fax, and over the telephone. To learn more about the MCPSS, please visit the CMS MCPSS website at http://www.cms.hhs.gov/mcpss or read the CMS Special Edition MLN Matters article, SE1005, located at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE1005.pdf on the CMS website.

MLN Matters Number: MM6839 | Related Change Request (CR) #: 6839

Related CR Release Date: March 5, 2010 | Effective Date: December 9, 2009

Related CR Transmittal #: R1925CP | Implementation Date: April 5, 2010

Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

Provider Types Affected

Physicians and providers who may wish to submit claims to Medicare Carriers, Fiscal Intermediaries (FIs) and Part A/B Medicare Administrative Contractors (A/B MACs) for PTA with stenting of the carotid arteries are affected.

Provider Action Needed

This article is based on Change Request (CR) 6839 which announces that for claims with dates of service on and after December 9, 2009, contractors will be aware that there is revised language specific to embolic protection devices (EPDs) for percutaneous transluminal angioplasty (PTA) concurrent with carotid artery stenting (CAS) system placement in Food and Drug Administration-Approved post-approval studies, and PTA Concurrent with CAS system placement in patients at high risk for carotid endarterectomy. The revised language specific to EPDs is located in Pub. 100-03, *National Coverage Determination (NCD)* 20.7.B.3 and

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20.7.B.4, and Pub. 100-04, Chapter 32, Section 160. Make sure your billing staff is aware of the revised language.

Background

Under the previous NCD policy, patients at high risk for carotid endarterectomy (CEA) who have symptomatic carotid artery stenosis ≥ 70 percent are covered for procedures performed using FDA-approved CAS systems with EPDs in facilities approved by the Centers for Medicare & Medicaid Services (CMS) to perform CAS procedures.

In addition, patients at high risk for CEA with symptomatic carotid artery stenosis between 50 percent and 70 percent and patients at high risk for CEA with asymptomatic carotid artery stenosis ≥ 80 percent are covered in accordance with the Category B Investigational Device Exemption (IDE) clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual* 310.1), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual* 20.7B). If deployment of the EPD is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

Policy:

CMS internally generated a reconsideration of Section 20.7B4 of the *Medicare NCD Manual.* CMS made no changes in the covered patient groups for PTA of the carotid artery concurrent with stenting, but slightly revised the language regarding EPDs. In the final decision, effective December 9, 2009, CMS retained existing coverage for the following with a slight revision to the language regarding EPDs:

- For patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥ 70 percent, coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs;
- For patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50 percent and 70 percent, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual* 310.1), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual* 20.7B), coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs. (If deployment of the EPD is not technically possible, and not performed, then the procedure is not covered.); and
- For patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80 percent, in accordance with the Category B IDE clinical

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trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual* 310.1), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual* 20.7B), coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs.

The use of an FDA-approved or cleared EPD is required. If deployment of the EPD is not technically possible and not performed, then Medicare does not cover the procedure.

NOTE: This CR does not require new or revised claims processing instructions.

Additional Information

For complete details regarding this Change Request, please see the official instruction (CR6839) issued to your Medicare Carrier, FI, or A/B MAC at *http://www.cms.hhs.gov/Transmittals/downloads/R1925CP.pdf* on the CMS website.

The CAS facilities "approved facilities" website link in Publication 100-03, *The National Coverage Determinations Manual*, may be found at *http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp* on the CMS website.

If you have questions, please contact your Medicare Carrier, FI, or A/B MAC, at their toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS website.

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